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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/509,951	10/04/2004	Gerardo Perez-Camargo	115808-509	3093

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K&L Gates LLP
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EXAMINER	
MAEWALL, SNIGDHA	

ART UNIT	PAPER NUMBER
1612	

NOTIFICATION DATE	DELIVERY MODE
06/12/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

chicago.patents@klgates.com

Office Action Summary	Application No.	Applicant(s)	
	10/509,951	PEREZ-CAMRGO,GERARDO	
	Examiner	Art Unit	
	Snigdha Maewall	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 March 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *35,37,39-41,43,45,48-52 and 54-68* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *35, 37, 39-41, 43, 45, 48-52 and 54-68* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Summary

1. Receipt of Applicant's arguments/remarks and amended claims all filed on 03/05/09 is acknowledged.

Claims 1-34, 36, 38, 42, 44, 46-47 and 53 have been cancelled.

Claims **35, 37, 39-41, 43, 45, 48-52 and 54-68** are pending in this application and claims **35, 37, 39-41, 43, 45, 48-52 and 54-68** will be prosecuted on the merits..

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 35, 37, 39-41, 43, 45, 48-52 and 54-68 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 1 recites the limitation that a liver function promoter comprises between about 0.1% to about 1.00% by weight of the edible composition. The specification on page 9, lines 30-35 discloses weight of only taurine. The amount is not disclosed for any

kind of liver function promoter as claimed such as glutathione promoters, glutathione or emulsifiers. This is a new matter rejection.

The limitation that a pet animal that has or is susceptible to, a vitamin deficiency is not disclosed in the specification. The specification only discloses a pet which is cat, see page 18. this is a new matter rejection.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5 Claims 35, 37, 39-41, 43, 45, 48-52 and 54-68 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 43 and 45 recite the limitation anti-inflammatory agent, claim 43 recites the limitation omega-3 fatty acid and a fatty acid having a profile specially selected to improve absorption makes the claim indefinite, no metes and bounds of claim can be deduced as recited. Appropriate corrections are requested. Claim 43 recites the limitation anti-inflammatory agent twice which is not further limiting in a Markush group. Applicants have not described in claim 1 any specific pancreatic function promoter or intestinal mucosa function promoter, it is not clear how an intestinal mucosa function promoter or pancreatic function promoter will increase lipid absorption and further improve vitamin E absorption. Claim 39 recites the limitation "emulsifiers, vitamins,

minerals and glutathione promoters. The metes and bounds of claim are not defined. Claim 41 recites the limitation "agent and carrier"., Appropriate correction is required.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 35, 37, 39-41, 43, 45, 48-52 and 54-68 are rejected 35 U.S.C. 103(a) as being unpatentable over US Patent No. 6,471,999 in view of US 5,290,571 ('571) or US 5,451,412 ('412) and further in view of (Simpson, KW and Michel, KE. Micronutrient status in patients with gastrointestinal disease. Proceedings ACVIM, Denver, CO, pp. 651-653, 2001), (Suzuki et al. Gastroenterology 1999; 116:431-437 7), (W0 01/62280) and (USP 6,228,367).

'999 teach a pet milk powder as nutritional milk those results in reduced gastrointestinal intolerance (abstract). '999 teaches that the milk powder when administered in an effective amount with the nutritional composition reduces gastrointestinal intolerance and that it may further comprise one or more lipid source, protein source, vitamins and minerals, and teaches a specific aspect which comprises lactose (of micro-organism origin), lactase, taurine, arginine and choline (claims 1-9; col. 2, lines 9-lines 26).

'999 teach including an alkali in the milk-based powder, (an alkali as pancreatic function promoter as claimed) which slows the pH, drop in the gastrointestinal tract (col. 2, lines 53-55). '999 teaches that a protein source of whey protein and further supplemented with taurine and a probiotic micro-organism which beneficially effects the host by improving its intestinal microbial balance, such as lactic acid (col. 3, lines 25-40). '999 teaches chicory fibers, inulin, fructooligosaccharides with the probiotic micro-organism (intestinal function promoter as claimed) have a symbiotic relationship for promoting beneficial effects (col. 4, lines 9-14).

'999 teaches that the amount of nutritional composition is to be fed to a mammal each day depends on factors such as age, type of mammal (dogs and cats), and other nutritional sources (col. 4, lines 25-36). Examples 1 and 2 teach mixing the milk powder, galactosidase (lactase amino), **vitamins (**a liver function promoter as claimed) minerals, and soybean oil, and adding water to provide nutritional supplement to dogs and puppies or cats. '999 teaches that a protein source of whey protein (a glutathione promoter as claimed) and further supplemented with taurine and a **probiotic micro-organism** which beneficially effects the host by improving its intestinal microbial balance, such as lactic acid (col. 3, lines 25-40). '999 teach omega fatty acids such as **soybean oil** (claimed as intestinal function promoter and intestinal function promoter) and in Examples 1-2 (col. 3, lines 15-20). Soybean oil and vitamin (claimed as liver function promoter) has been shown to be at 1.7 percent by weight and 0.4% by weight respectively in Example 1 in column 4. The amount of soybean oil (a fatty acid with

profile and intestinal function promoter as claimed) is within the claimed range of between about 0.1% to 20%.

'999 does not characterize whey protein as glutathione promoter.

However, 571 or 412 correlate whey protein as glutathione promoters and teach glutathione promoters.

'571 or '412 teach a composition of whey protein concentrate (abstract).

'412 claims 1 and 2 teach compositions containing whey protein concentrate that promote glutathione as nutritional supplements to animals. The reference teaches immuno-enhancing effect maximized at 20%, see column 12, lines 48-58.

'571 teaches that a suitable source of whey protein is known by the trademark PROMOD, which contains whey protein and soy lecithin (col. 5, lines 34-41). Soy lecithin is taught by applicant in instant Example 2 to be an appropriate liver function promoter. '571 teaches that glutathione GSH promotion is a major function of the whey protein concentrate (w.p.c.) (col. 1, lines 30-37). '571 teaches the production of glutathione in the spleen, heart, liver is greater in mice fed with w.p.c, than mice fed with egg white protein (col. 4, lines 39-46).

The reference teaches use of about 18-28 gm of whey protein per 100 grams (18-20%.)., see claim 1.'571 teaches that the object of the invention is to provide a method for increasing the concentration level of glutathione in the organs and enhancing resistance to bacterial infection of mammals through the use of w.p.c, via oral administration (col. 10, lines 46-57). '571 also teaches inclusion of vitamins B1 and B2 with w.p.c. (claim 1-3, col. 11, lines 55-57).

The references disclosed above do not teach lipid assimilation, however, Simpson et al. disclose that vitamin E is a fat-soluble vitamin that is absorbed only with long chain fatty acids. A defect in either the absorption or digestion of lipid can therefore lead to deficiencies in this and other vitamins, due to their binding with unabsorbed fatty acids (Simpson, KW and Michel, KE. Micronutrient status in patients with gastrointestinal disease. Proceedings ACVIM, Denver, CO, pp. 651-653, 2001). Hence, a pet with low lipid digestibility is susceptible to several potential nutritional deficiencies, which can compromise its health. (See the entire articles of record).

A skilled artisan would thus have been motivated to provide a pet with an edible composition comprising liver function promoter in order to help in lipid assimilation which in turn helps in improving vitamin E absorption with a reasonable expectation of success based on the teachings of the disclosed references.

It would have been obvious to one of ordinary skill in the art to optimize the amount of liver function promoter such as glutathione promoters to obtain best possible results by doing experimental manipulations because '999 teaches soybean oil (reads on both liver function promoter and intestinal function promoter) and vitamins in 1.7% and 0.4% amount (claimed as liver function promoter), as such it would have been within the purview of a skilled artisan to optimize the amount of glutathione, emulsifiers, taurine or any other liver function promoter to obtain best possible results and come to the claimed invention.

'999 does not teach pancreatic function promoter such as lipase. (a pancreatic function promoter)

367 claims in claim 1 a food supplement formulation of fish oil and lipase (the instant specification defines a pancreatic extract to be a lipase pg. 12, lines 1-3) (abstract, claim 1). The supplement of '367 improves bodily functions including fat metabolism, etc (col. 2, lines 26-30). The fish oil has specific fatty acid profile.

'999 and '367 references do not correlate the pancreatic function promoter (lipase) and intestinal mucosa function promoter such as probiotic microorganism with lipid absorption. Suzuki et al. disclose that bacterial or porcine Lipase with high or low fat diets optimizes fat absorption (see the entire article of record). It would have been obvious to the one of ordinary skilled in the art at the time the invention was made to incorporate pancreatic function promoter and intestinal mucosa function promoter in a feed composition and improve lipid absorption capacity of a pet animal with a reasonable expectation of success. WO '280 correlates the lipid absorption capacity with vitamin E absorption. As such, the pancreatic function promoter would have improved vitamin E absorption with the enhanced absorption of lipid in a pet animal in view of WO.

A skilled artisan would thus have been motivated to formulate a composition comprising liver function promoter, pancreatic function promoter and intestinal function promoter with a reasonable expectation of success in order to help increase lipid absorption and vitamin E absorption of a pet animal. Optimization of amounts would have been within the purview of a skilled artisan by doing experimental manipulations since the amounts depend on age, type of mammal, severity of vitamin deficiency, disease condition and condition of the mammal used, absent evidence to contrary.

Response to Arguments

8. Applicant's arguments with respect to claims 35, 37, 39-41, 43, 45, 48-52 and 54-68 have been considered but are moot in view of the new ground(s) of rejection.

9. Claims 35, 37, 39-41, 43, 45, 48-52 and 54-68 are rejected 35 U.S.C. 103(a) as being unpatentable over US Patent No. Fuchs et al WO 02/15719 ('719) in view of US 5,290,571 ('571) or US 5,451,412 ('412) and further in view of (Simpson, KW and Michel, KE. Micronutrient status in patients with gastrointestinal disease. Proceedings ACVIM, Denver, CO, pp. 651-653, 2001), (Suzuki et al. Gastroenterology 1999; 116:431-437 7), (W0 01/62280) and (USP 6,228,367).

'719 discloses a method of treatment which comprises administering an effective amount of the composition which contains whey protein to improve, promote, maintain intestinal function and mucins a patient or companion animal (abstract, claims 1-2 and 14-20, pg. 6 lines 5-10; pg. 12 lines 3-21).

Example 4 teaches a nutritional supplement comprising whey protein and probiotic bacteria. '719 teaches that the nature of whey protein and the fact that it is capable of being easily digested, the composition has a beneficial effect in patients with limited appetite due illness, surgery, chronic gastritis, etc (pg. 4, line 31-pg. 5, line 6), and that the addition of a probiotic micro-organism (pancreatic function promoter as claimed) provides the advantage of restoring the natural balance of the intestinal flora following antibiotic therapy (pg. 6, lines 7-10). Whey protein is taught by applicant to be

a fat transportation aid agent and carrier (instant spec pg. 10, 13-20). The amount of Whey protein is taught to be 4.8% and vitamins and minerals to at least 5% of RDA in example 1 on page 13 , '719 also teaches including a prebiotic (claim 13, pg. 5, lines 27-30). '719 teach including **taurine and** (claim 12, pg. 5, lines 18-25; pg. 6, lines 27-29), (claimed as liver function promoter in instant claims) . '719 teaches a lipid source including omega-3 fatty acids (abstract, claim 1). (claimed as intestinal function promoter in instant claims).

'719 teaches a nutritional supplement comprising whey protein and omega-3 fatty acids (abstract, claims 1-2). The reference teaches various amounts of polyunsaturated fatty acids including omega 3 fatty acid to be 15 to 30%, see page 8, lines 10-20. The reference teaches vitamins (claimed as liver function promoter in instant application), see page 9, lines 1-14.

'719 does not teach liver function promoter such as glutathione or glutathione promoters. However, 571 or 412 teach glutathione. '571 or '412 teach a composition of whey protein concentrate (abstract).

'412 claims 1 and 2 teach compositions containing whey protein concentrate that promote glutathione as nutritional supplements to animals. The reference teaches immuno-enhancing effect maximized at 20%, see column 12, lines 48-58.

'571 teaches that a suitable source of whey protein is known by the trademark PROMOD, which contains whey protein and soy lecithin (col. 5, lines 34-41). Soy lecithin is taught by applicant in instant Example 2 to be an appropriate liver function promoter. '571 teaches that glutathione GSH promotion is a major function of

the whey protein concentrate (w.p.c.) (col. 1, lines 30-37). '571 teaches the production of glutathione in the spleen, heart, liver is greater in mice fed with w.p.c, than mice fed with egg white protein (col. 4, lines 39-46).

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It would have been obvious to one of ordinary skill in the art to optimize the amount of liver function promoter such as glutathione promoters to obtain best possible results by doing experimental manipulations because '719 teaches vitamin (claimed as liver function promoter) to be in supplied about 50 to 500% and in at least 5% of RDA, see example 1 on page 5, as such it would have been within the purview of a skilled artisan to optimize the amount of glutathione promoters such as whey protein within the claimed amount with a reasonable expectation of success.

The references disclosed above do not teach lipid assimilation, however, Simpson et al. disclose that vitamin E is a fat-soluble vitamin that is absorbed only with long chain fatty acids. A defect in either the absorption or digestion of lipid can therefore lead to deficiencies in this and other vitamins, due to their binding with unabsorbed fatty acids (Simpson, KW and Michel, KE. Micronutrient status in patients with gastrointestinal disease. Proceedings ACVIM, Denver, CO, pp. 651-653, 2001). Hence,

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A skilled artisan would thus have been motivated to formulate a composition comprising liver function promoter, pancreatic function promoter and intestinal function promoter with a reasonable expectation of success in order to help increase lipid absorption and vitamin E absorption of a pet animal. Optimization of amounts would have been within the purview of a skilled artisan by doing experimental manipulations since the amounts depend on age, type of mammal, severity of vitamin deficiency, disease condition and condition of the mammal used, absent evidence to contrary.

Response to Arguments

10. Applicant's arguments with respect to claims 35, 37, 39-41, 43, 45, 48-52 and 54-68 have been considered but are moot in view of the new ground(s) of rejection.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Snigdha Maewall whose telephone number is (571)-272-6197. The examiner can normally be reached on Monday to Friday; 8:30 a.m. to 5:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-0580. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status

information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Snigdha Maewall/

Examiner, Art Unit 1612

/Gollamudi S Kishore/

Primary Examiner, Art Unit 1612